

**Meghan Handy**, Individually and as Surviving Child and Personal Representative of the Estate of Brenda Lee Rozek, Deceased  
8 Rollins Road  
North East, Maryland 21901

and

**Neil E. Rozek**  
761 Ragan Road  
Conowingo, Maryland 21918

and

**Kristen Lowery**  
761 Ragan Road  
Conowingo, Maryland 21918

and

**Frank D. Ragan, Sr.**  
440 Johnson Road  
Conowingo, Maryland 21918

and

**JoAnne Ragan**  
440 Johnson Road  
Conowingo, Maryland 21918

Plaintiffs,

v.

**BOX HILL SURGERY CENTER, LLC**  
100 Walter Ward Boulevard  
Suite B2  
Abingdon, Maryland 21009

Serve on:

L. Stephen Hess, Esq.  
26th Floor  
2100 East Pratt Street  
Baltimore, MD 21202

and

**IN THE  
CIRCUIT COURT  
FOR  
BALTIMORE COUNTY**

Case No.: 03-C-14-009238

**Complaint and Demand  
for Jury Trial**

RECEIVED AND FILED  
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BALTIMORE COUNTY

EXHIBIT

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**RITU T. BHAMBHANI, M.D.**

496 Rutland Drive  
Fallston, Maryland 21047

Serve on:  
Ritu T. Bhambhani, M.D.  
496 Rutland Drive  
Fallston, Maryland 21047

and

**RITU T. BHAMBHANI, M.D., LLC**  
496 Rutland Drive  
Fallston, Maryland 21047

Serve on:  
Resident Agent:  
Ritu T. Bhambhani, M.D.  
496 Rutland Drive  
Fallston, Maryland 21047

and

**Barry J. Cadden**  
13 Manchester Drive  
Wrentham, Massachusetts 02093

Serve on:  
Barry J. Cadden  
13 Manchester Drive  
Wrentham, Massachusetts 02093

and

**Gregory Conigliaro**  
1 Mountain View Drive  
Framingham, Massachusetts 01701

Serve on:  
Gregory Conigliaro  
1 Mountain View Drive  
Framingham, Massachusetts 01701

and

**Lisa Conigliaro Cadden**  
13 Manchester Drive  
Wrentham, Massachusetts 02093

Serve on:  
Resident Agent:  
Lisa C. Cadden  
13 Manchester Drive  
Wrentham, Massachusetts 02093

and

**Douglas Conigliaro;**  
15 Hale Drive  
Dedham, Massachusetts 02026

and

Serve on:  
Douglas Conigliaro;  
15 Hale Drive  
Dedham, Massachusetts 02026

and

**Carla Conigliaro**  
15 Hale Drive  
Dedham, Massachusetts 02026

Serve on:  
Carla Conigliaro  
15 Hale Drive  
Dedham, Massachusetts 02026

and

**Glenn A. Chin**  
173 Mechanic Street  
Canton, Massachusetts 02021

Serve on:  
Glenn A. Chin  
173 Mechanic Street  
Canton, Massachusetts 02021

and

( )  
**Ameridose, LLC**  
203 Flanders Road  
Westborough, Massachusetts, 01581

Serve on:  
Resident Agent:  
Ameridose, LLC  
203 Flanders Road  
Westborough, Massachusetts, 01581

and

( )  
**GDC Properties Management, LLC**  
701 Waverly Street  
Framingham, Massachusetts 01702

Serve on:  
Resident Agent:  
GDC Properties Management, LLC  
701 Waverly Street  
Framingham, Massachusetts 01702

and

( )  
**Medical Sales Management, Inc.**  
697 Waverly Street  
Framingham, Massachusetts 01702

Serve on:  
Resident Agent:  
Medical Sales Management, Inc.  
697 Waverly Street  
Framingham, Massachusetts 01702

and

( )  
**Medical Sales Management SW, Inc.**  
697 Waverly Street  
Framingham, Massachusetts 01702

Serve on:  
Resident Agent:  
Medical Sales Management SW, Inc.  
697 Waverly Street  
Framingham, Massachusetts 01702

( )  
and

**ARL Bio Pharma, Inc. D/B/A Analytical Research Laboratories**  
840 Research Parkway  
Suite 546  
Oklahoma City, Oklahoma 73104

Serve on:  
Resident Agent  
ARL Bio Pharma, Inc.  
840 Research Parkway  
Suite 546  
Oklahoma City, Oklahoma 73104

and

**Liberty Industries, Inc.**  
133 Commerce Street  
East Berlin, Connecticut 06023

Serve on:  
Resident Agent  
**Liberty Industries, Inc.**  
133 Commerce Street  
East Berlin, Connecticut 06023

and

**UniFirst Corporation (d/b/a "Uniclean Cleanroom Services")**  
68 Jonspin Road  
Wilmington, MA 01887

Serve on:  
Resident Agent  
**UniFirst Corporation**  
8820 Yellow Brick Rd.  
Baltimore, MD 21237

Defendants.

**COMPLAINT AND DEMAND FOR JURY TRIAL**

COME NOW the Plaintiffs, Meghan Handy, individually, as surviving child and as Personal Representative of the Estate of Brenda L. Rozek, deceased ("Decedent"), together with

167. As a result of failures and omissions, UniFirst (solely or in concert with NECC) negligently allowed contaminants such as *aspergillus* into every cleanroom where recalled products were made, composed, mixed, prepared, packaged and stored.

168. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into the NECC facility, including its anterooms and cleanrooms. UniFirst did not conduct appropriate due diligence to follow its own policies and procedures, and failed to follow NECC policies and procedures when in that facility.

#### **PERTINENT MARYLAND AND MASSACHUSETTS LAW**

169. The Code of Maryland Regulations (hereinafter "COMAR") provides quality of care licensing standards for health care providers and facilities that are licensed by the Office of Health Care Quality. Under Title 10 Department of Health and Mental Hygiene Subtitle 05 Freestanding Ambulatory Care Facilities, 10.05.01.06 (D) Policies and Procedures, the administrator, in consultation with the medical director, shall develop and implement policies and procedures governing the operation of the facility which include at a minimum: ... (8) Infection control for patients and staff; ... E. The administrator shall ensure that all: ... (3) Appropriate personnel implement all policies and procedures as adopted.

170. COMAR 10.05.05.10 Pharmaceutical Services provides: A. The freestanding ambulatory surgical facility shall: (1) Provide drugs and biological under the direction of an authorized prescriber; and (2) Develop and implement policies and procedures for pharmacy services in accordance with accepted professional practice. B. Administration of Drugs. (1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice.

171. COMAR 10.34.19.08 Batch Preparation states: (A) A pharmacist may prepare batched sterile preparations for future use in limited quantities supported by prior valid prescriptions or physician orders before receiving a valid written prescription or medication order. (B) Batch preparation of specific compounded sterile preparations is acceptable if the: (1) Pharmacist can document a history of valid prescriptions or physician orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship and (2) Pharmacy maintains the prescription on file for such preparations dispensed.

172. COMAR 10.34.19.06 (B) states: "The dispensed container for any compounded sterile preparation shall include labeling according to Maryland law and regulations, in addition to the following information that is required by federal law: ... (5) The name of the patient"

173. In order to purchase compounded drugs from NECC, it was necessary for both NECC and the Health Care Providers to comply with Massachusetts state law, which governed the compounding and dispensing activities of NECC according to Massachusetts law where and when, as here, a Massachusetts pharmacy is asked to fill and dispense a controlled substance prescribed by an out-of-state licensed prescriber.

174. Massachusetts law does not permit the practice of ordering and dispensing compounded drugs for office use, requiring instead an individual prescription for a specific named patient. Massachusetts General Law Chapter 94C and Department of Public Health regulations (Code of Massachusetts Regulations §721.000) require that pharmacies and pharmacists dispense medications pursuant to a valid prescription from an authorized practitioner for a specific patient. This prescription must be valid as defined under Massachusetts statutes and regulations, not under the rules governing prescriptions in the recipient state.<sup>1</sup> These laws

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<sup>1</sup> The Commonwealth of Massachusetts Executive Office of Health and Human Services, Department of Public Health, Division of Health Professionals Licensure, Board of Registration in Pharmacy, *Advisory:*

provide that that writing prescriptions for the “general dispensing to patients”<sup>2</sup> is forbidden; that the name of a particular patient and prescribing doctor appear on the prescription;<sup>3</sup> and regulations require that the name and address of a particular patient be present on a prescription’s label. Massachusetts prescription dispensing policy thereby maintains the traditional physician-pharmacist- patient relationship, thereby greatly increasing the likelihood that compounded drugs will be used in a timely and safe manner.

175. The Maryland Consumer Protection Act (hereinafter “CPA”) establishes minimum standards of conduct in the marketplace to protect consumers. To establish a violation of the CPA, a Claimant must prove that the Defendant engaged in unfair and deceptive trade practices in connection with the sale or offer for sale of consumer goods, causing the Claimant to sustain injury. *Morris v. Osmose Wood Preserving*, 340 Md. 519, 538-539 (1995). The deceptive practice must occur in the sale or offer for sale to consumers. A private party suing under the CPA must establish actual injury or loss. *Id.* at 538.

176. The Massachusetts analog to Maryland’s Consumer Fraud Act is Mass. Gen. Laws Ann. Ch. 93A et seq. (“**Chapter 93A**”) Chapter 93A also prohibits false representations deceptive acts and practices and makes violations of statutes, regulations and guidelines intended to protect consumers safety a *per se* violation of the Act, giving rise to a private cause of action for damages, multiple damages, fees and costs.

177. Maryland’s CPA and Massachusetts’ Chapter 93A are not mutually exclusive laws and both Acts constitutionally and textually may and should apply at the same time to the misconduct of a party herein because both State’s laws prohibit and proscribe the misconduct

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*Compounding Pharmacies and Pharmacists* (October 2012),  
<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy-alert-compounding.pdf>.

<sup>2</sup> Mass. Gen. Laws Ann. ch. 94C, § 19.

<sup>3</sup> Mass. Gen. Laws Ann. ch. 94C, § 22.

309. Plaintiff, Neil E. Rozek, claims all allowable damages for Wrongful Death under Maryland law. He also claims loss of income and support from his late wife as a result of her

310. As a further proximate result of the Defendants' negligence and other tortious conduct alleged above, Plaintiffs, Neil E. Rozek, Meghan Handy, Kristen Lowery, Frank D. Ragan, Sr. and JoAnne Ragan, each has suffered mental anguish, emotional pain and suffering, loss of society, loss of companionship, loss of comfort, loss of attention, loss of advice, loss of counsel, and loss of guidance and claims all allowable damages under Maryland's wrongful death law for the loss of Brenda L. Rozek, deceased.

**WHEREFORE**, Plaintiffs pray for relief as follows:

- (a) Compensatory damages in an amount in excess of \$30,000.00 for malpractice claims against the Defendants and in excess of \$75,000 on all other claims;
- (b) Punitive damages under the laws of Maryland, Massachusetts and/or other applicable law;
- (c) All costs and attorneys' fees recoverable by law; and
- (d) Such other and further relief as the Court deems appropriate.



ROBERT J. WELTCHEK  
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NOLAN J. WELTCHEK  
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*Of Counsel:*

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Philadelphia, Pennsylvania 19103  
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**DEMAND FOR JURY TRIAL**

Plaintiffs elect to have their case tried before a jury.



ROBERT J. WELTCHEK